UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE: AVANDIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	**MDL 1871** **2:07-md-01871-CMR**
THIS DOCUMENT RELATES TO:	**AMENDED COMPLAINT**
2:07-cv-04964-CMR	**Jury Trial Demanded**

Plaintiff Michael Miracolo, by and through his undersigned counsel, brings this action individually against GlaxoSmithKline, Inc., d/b/a SmithKline Beecham Corp; GlaxoSmithKline, PLC, f/k/a SmithKline Beecham Corp., hereinafter referred to either individually or collectively as "Defendants" or "GSK" and alleges as follows:

NATURE OF THE ACTION

1. This is an action to recover damages for injuries sustained by Plaintiff as the direct and proximate result of Defendants' wrongful conduct in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of the widely-used diabetes prescription drug Avandia® (rosiglitazone).

PARTIES

2. At all times relevant, Plaintiff was a resident of Nassau County, New York and brings this action to recover damages for injuries sustained as a result of Plaintiff ingesting Avandia®.

3. GlaxoSmithKline is incorporated under the laws of Pennsylvania and has its principal place of business in the United States at One Franklin Plaza, 200 N. 16th Street, Philadelphia, Pennsylvania. GSK is the surviving entity from the following mergers:

a. On May 7, 1995, GSK merged into Burroughs Wellcome Co. In connection with that merger, Burroughs Wellcome Co. changed its name to Glaxo Wellcome, Inc.; and

b. On March 31, 2001, Glaxo Wellcome, Inc. merged with GSK.

4. As the surviving entity, GSK is liable for the actions and inactions of all the companies involved in the mergers. GSK is engaged in manufacturing, marketing, promoting, selling and/or distributing the drugs Avandia®, Avandamet®, and Avandaryl® and regularly conducts business within the State of New York and within the Eastern District of New York and derives substantial revenues from goods consumed in New York and within the Eastern District of New York.

5. At all relevant times, Defendants were engaged in the business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, distributing and/or selling the prescription drug product Avandia®, Avandamet®, and Avandaryl® (hereinafter referred to individually or collectively as "Avandia®" or "rosiglitazone") as an antidiabetic medication to the general public including Plaintiff.

6. At all relevant times, Defendants were authorized to do business within the State of New York and did in fact supply Avandia® within the State of New York.

FACTUAL ALLEGATIONS

7. GSK manufactures, promotes, distributes, labels, and markets rosiglitazone under the trade names of Avandia®, Avandamet®, and Avandaryl®.

8. Rosiglitazone is a member of a class of drugs known as Thiazolidinediones ("TZDs").

9. Avandia® was first approved for use in the United States in 1999 for the use in treatment of type 2 diabetes mellitus, also known as non-insulin-dependent diabetes mellitus ("NIDDM") or adult-onset diabetes.

10. In 2002, Avandamet®, a single pill combination of Avandia® and metformin, was approved in the United States for use in treatment of type 2 diabetes mellitus.

11. In 2005, Avandaryl®, a single pill combination of Avandia® and Amaryl®, likewise was approved in the United States for use in treatment of type 2 diabetes mellitus.

12. Type 2 diabetes is the most common form of diabetes and occurs where the body fails to properly use insulin (insulin resistance), combined with relative insulin deficiency.[1] Insulin, which is made in the pancreas, helps the body's cells use sugar from the bloodstream, which comes from foods and drinks. Sugar is a source of energy for cells.[2]

13. Most people with diabetes have health problems -- or risk factors -- that increase the risk of heart disease or stroke or other severe injury. More than 65% of people with diabetes die from heart disease or stroke.

14. Cardiovascular disease is the main cause of death in these patients. Thus, it is important that an antidiabetic agent reduce the risk of cardiovascular injury.

15. During the past decade, numerous drugs have been introduced for the treatment of type 2 diabetes that, used in monotherapy or in combination therapy, are supposed to

---

[1] http://www.diabetes.org/about-diabetes.jsp

[2] *Id.*

better control the disease in patients and reduce the health complications often associated with diabetes, such as heart attacks, strokes and other cardiovascular complications.

16. TZDs are a novel class of insulin-sensitizing antidiabetic agents. In the USA and Canada, two TZDs are indicated for use in type 2 diabetes mellitus, rosiglitazone, and pioglitazone. A third, troglitazone (Rezulin) has been removed from the market because of an association with significant hepatotoxicity.

17. At all relevant times, GSK was in the business of designing, licensing, promoting, manufacturing, marketing, selling, and distributing pharmaceuticals and other products, including Avandia®.

18. GSK is licensed to do business and in fact does business by agent in the State of New York. At all relevant times, GSK designed, developed, licensed, marketed, manufactured, sold and placed in the stream of commerce Avandia®, including the Avandia® at issue in this lawsuit. GSK did this throughout the United States, in Nassau County, and in the State of New York.

19. Plaintiff purchased and used Avandia®, which had been prescribed for him by a physician licensed in the State of New York and he used it as prescribed.

20. Avandia® was manufactured, sold, distributed, and placed in the stream of commerce by Defendants.

21. At the time Plaintiff began to use Avandia®, he did not know, and could not have known, that Avandia® was defective and would cause severe injury and death.

22. Plaintiff did not know, and could not have known, that prior to the date he used Avandia®, Defendants were aware and had knowledge that Avandia® which it manufactured, marketed, sold and distributed was defective and had the propensity to cause severe injury including death.

23. In fact, Defendants knew as early as 1999 that Avandia® was unreasonably dangerous and could cause heart attacks and deaths.

24. In 1999, Dr. John B. Buse (the current president-elect of the American Diabetes Association), a diabetes expert and head of endocrinology at the University of North Carolina, Chapel Hill, raised concerns about Avandia® and heart problems, including the risk of heart attack and death.

25. GSK attempted to silence Dr. Buse and further conceal the true nature of Avandia® risks by threatening Dr. Buse with a $4 Million lawsuit and by characterizing him as a liar.[3]

26. In response to Defendants' pressure, Dr. Buse sent a three-page letter to Dr. Tadataka Yamada, GSK's Chairman of Research and Development. In the letter, Dr. Buse wrote, "I may disagree with GSK's interpretation of that data. . . . I am not for sale . . . . Please call off the dogs. I cannot remain civilized much longer under this kind of heat."

27. On March 15, 2000, Dr. Buse wrote a letter to the FDA again raising concerns about a "worrisome trend in cardiovascular deaths and severe adverse events" associated with Avandia®:

> I would like you to know exactly what my concerns are regarding rosiglitazone as a clinical scientist and my approach as a clinician. On the basis of the increase in LDL concentration seen in the clinical trial program (whether the number we accept as the truth is the 18.6% at 4 mg bid in the package insert or the "average of 12%" now being discussed) one would expect an increase in cardiovascular events. . . . Based on studies with statins and plasmapheresis, changes in LDL concentration can be associated with substantial changes in vascular reactivity and endothelial function over a time course of days to weeks.[4]

---

[3] John Buse, M.D. Congressional Hearing Transcript (June 6, 2007).

[4] Letter from Dr. Buse to FDA (March 15, 2000).

28. Dr. Buse was not the only person to alert GSK to the increased risk of heart attack and death associated with Avandia®. Shortly after Dr. Buse raised concerns related to increased risk of heart attacks associated with Avandia®, Public Citizen filed a petition, on March 7, 2000, seeking immediate class labeling changes for all marketed TZDs,[5] including rosiglitazone.

29. In an independent investigation of the TZDs, Public Citizen, after studying reviews by FDA Medical Officers, Statisticians, and Pharmacologists, transcripts of FDA advisory committee meetings, and scientific literature on trolitazone, rosiglitazone, and pioglitazone, argued that information associating rosiglitazone to heart attacks and serious cardiovascular injuries "was never included in the label, or seriously understated."[6]

30. Public Citizen cited studies submitted to the FDA for approval that evidenced lack of efficacy and increase in cardiovascular risks, including but not limited to the increased risk of suffering a heart attack.

31. Public Citizen argued that nowhere in the product insert was there any mention of myocardial infarction even where the increased risk of myocardial infarctions was found in GSK's own studies.

32. Public Citizen pointed to several studies, many of which were studies conducted by GSK. The conclusion reached by Public Citizen was that rosiglitazone was not as effective as alleged and the ingestion of rosiglitazone increased the risk of myocardial infarction, death and other serious cardiovascular injuries.[7]

---

[5] Public Citizen's Petition to the FDA requesting that it immediately require labeling for diabetes drugs troglitazone (Rezulin), rosiglitazone (Avandia) and pioglitazone (Actos) (HRG Publication #1514) (March 7, 2000).

[6] *Id.* at 1.

[7] *Id.* at 6.

33. This is obviously a major concern since diabetics are already susceptible to an increased risk of cardiovascular injury.

34. In addition to the concerns raised by Dr. Buse and Public Citizen, there have also been three meta-analyses conducted. Each meta-analysis has found that Avandia® increases the risk of cardiovascular-related injury, including but not limited to myocardial infarction and death.

35. A meta-analysis combines the result of several studies that address a set of related research hypotheses.

36. The first analysis was performed by GSK and was handed over to the FDA in August of 2006. The meta-analysis consisted of 42 separate double-blinded, randomized, controlled clinical trials to assess the efficacy of rosiglitazone for treatment of type 2 diabetes compared to either placebo or other antidiabetic therapies in patients with type 2 diabetes. The combined studies included 8,604 patients on rosiglitazone and 5,633 patients randomized to a variety of alternative therapeutic regimens, including placebo.

37. GSK's own meta-analysis found an overall incidence of myocardial ischemia in rosiglitazone-treated subjects. The risk equated to more than a 30 percent excess risk of myocardial ischemic events in rosiglitazone-treated patients.

38. A second meta-analysis conducted by Dr. Steven Nissen and Kathy Wolski titled Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes was published on May 21, 2007, in the New England Journal of Medicine (NEJM).

39. Nissen and Wolski reviewed data available to them through published literature, the FDA website, and GlaxoSmithKline's clinical-trials registry. The analysis included a review of 42 clinical trials involving nearly 28,000 patients.

40. Nissen and Wolski concluded that "[r]osiglitazone was associated with a significant increase in the risk of myocardial infarction and with an increase in the risk of death from cardiovascular causes that had borderline significance." [8]

41. Hence, it was found that patients suffering from Type 2 diabetes mellitus have a higher risk of experiencing a heart attack within seven years than non-diabetic patients. But a diabetic taking Avandia® has a much greater risk of suffering a heart attack or serious cardiovascular event - an estimated 43 percent increase or greater -when compared with other diabetes drugs or placebos.

42. On July 30, 2007, the FDA presented its results of the FDA meta-analysis. Similar to the GSK and Nissen/Wolski findings, the FDA likewise found an increase risk of heart attack, stroke and other serious ischemic related adverse events and ultimately recommended that a boxed warning be placed on the Avandia® label.

43. Thus, while GSK's rosiglitazone-containing drugs are marketed and sold by GSK as antidiabetic agents that reduce a diabetic patient's risk of heart attacks, studies conducted by GSK showed that rosiglitazone actually increases those risks by 43 percent according to the Nissen/Wolski meta-analysis and by 31 percent according to GSK's own meta-analysis.

44. Yet, even with this information available to it, GSK failed to warn consumers and the medical community about the increased risk of heart attacks and other serious injuries associated with Avandia®.

45. Moreover, Defendants have repeatedly engaged in a pattern of conduct of deliberately avoiding FDA recommendations as to which issues relating to public hazards should be warned about.

---

[8] Nissen S.E. and Wolski K., *Effects of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes, N Engl J Med;* 356, May 21, 2007.

46. For instance, after the FDA required GSK to change its label on February 8, 2001, to reflect a risk of heart failure observed in patients on Avandia® and insulin, GSK defied FDA recommendations by engaging in false and misleading promotional activities.

47. In a letter dated February 22, 2001, the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") informed GSK that all promotional materials for Avandia® should be revised to prominently include the new risks, no later than March 8, 2001.

48. GSK responded on March 1, 2001, wherein GSK committed to include the new risk information by March 8, 2001.

49. However, instead of complying with FDA requirements GSK's sales representatives engaged in false or misleading promotional activities with respect to the new risk information in Avandia®'s product labeling.

50. In a Warning Letter dated July 17, 2001, the FDA warned GSK that it had engaged in a continual violation of federal regulations in its promotional activities for the marketing of Avandia®.

51. In that July 17, 2001 letter, the FDA warned that the DDMAC had been monitoring its marketing of Avandia® and had:

> [C]oncluded that GSK has promoted Avandia in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. See 21 U.S.C. §§ 331(a),(b), and 352(a),(n).
>
> Specifically, during the 10th Annual American Association of Clinical Endocrinologists (AACE) Meeting in San Antonio, Texas, on May 2-6, 2001, representatives of GSK made oral representations denying the existence of serious new risks associated with Avandia at GSK's promotional exhibit booth. Additionally, GSK displayed Exhibit panels (AV013G) at the meeting that minimized these new risks associated with Avandia.
>
> Your promotional activities that minimize serious new risks are particularly troublesome because we have previously objected, in two untitled letters, to

> your dissemination of promotional material for Avandia that failed to present any risk information about Avandia or minimized the hepatic risk associated with Avandia. Despite your assurances that such violative promotion of Avandia had ceased, your violative promotion of Avandia has continued.[9]

52. Following the May 21, 2007 NEJM publication of the Nissen/Wolski meta-analysis, the FDA issued a safety alert for Avandia® and advised patients who take it to consult their doctors.

53. On June 1, 2007, GSK published a "Dear Avandia Patient" letter, which responded to the "recent press coverage about the safety of Avandia." Therein, GSK stated that it "stands firmly behind Avandia" and that "Avandia is the most widely studied medicine for type 2 diabetes" and that the evaluation of clinical trials by "well-informed experts and researcher has been encouraging."

54. At the congressional hearing on June 6, 2007, the FDA indicated that a black box warning should be added to rosiglitazone (*i.e.*, Avandia®), for increased risk of heart failure.

55. On July 30, 2007, the FDA held an Advisory Committee Hearing on the safety of Avandia®. The panel was determining whether to recommend keeping the label the same, adding a black box warning, or taking Avandia® off the market all together.

56. Dr. David Graham, testifying on behalf of the FDA, called for withdrawing Avandia® and estimated that its toxic effects on the heart had caused up to 205,000 heart attacks and strokes, some fatal, from 1999 to 2006. For every month that Avandia® is sold, Dr. Graham said, 1,600 to 2,200 patients will suffer more of those problems.

---

[9] Letter from Thomas Abrams, R.Ph., MBA, Director of the FDA's Division of Drug Marketing, Advertising and Communications to JP Garnier, Chief Executive Officer, GlaxoSmithKline (July 17, 2001) (on file with the FDA).

57. The FDA provided testimony that Avandia® offers no unique benefits compared to other drugs in battling diabetes, but that all indications point to increased risks of heart attack and sudden death.

58. The panel of advisers to the Food and Drug Administration voted 20-to-3 that Avandia® increases the risks of heart attacks.

59. Despite knowing of this defect prior to the date of Plaintiff's heart attack due to the use of Avandia®, Defendants took inadequate steps to advise physicians, hospitals, nursing homes and other health care providers of the possibility of heart attacks and death.

60. Despite having actual notice of the dangerous propensities associated with Avandia®, prior to the date Plaintiff purchased and used Avandia®, Defendants took inadequate steps to advise consumers or medical providers, including Plaintiff of the known dangers of Avandia® consumption, including but not limited to the increased risk of heart attack and death. Defendants failed to take adequate steps to ensure that the Avandia® it manufactured was safe for the public and would function in the manner it which they were intending.

61. The Avandia® ingested by Plaintiff was defective in that it exposed him to the risk of suffering a heart attack. As a result of using said Avandia®, Plaintiff suffered a heart attack as a direct and proximate result of his ingestion of Avandia®.

62. Even after being made aware of the numerous reports of myocardial infarctions, including those adverse events that occurred during GSK's own studies, Defendants still failed to take all reasonable and necessary steps to ensure that the consuming public, including Plaintiff, was aware of the increased risk of suffering a heart attack or death. As stated in the above, Defendants knew that Avandia® caused heart attacks and deaths.

63. Plaintiff alleges that GSK was aware of the dangerous propensity of Avandia® referred to herein, that they knew the risks and dangers posed to those using Avandia®, and Defendants acted with willful and wanton disregard for the safety of the consuming public, including Plaintiff.

64. Defendants have widely promoted the use of Avandia® as a safe and effective method of treating type 2 diabetes mellitus.

65. Due to the efforts of Defendants, sales of Avandia® rose to more than three billion ($3,246,555,709.7600) dollars in 2006.[10]

66. GSK's net income (adjusted earnings) in 2006 was approximately $10.6 billion.

67. As a result of Defendants' efforts and actions, the sales of Avandia® have become an enormous source of profits for Defendants.

68. Accordingly, Defendants had a significant financial incentive to suppress, misrepresent, and/or conceal any potential dangers or risks associated with Avandia®.

69. Plaintiff asserts that GSK acted for the purpose of maximizing profits at the expense of the health of Plaintiff, and the health of others using Avandia®. Plaintiff further asserts that Defendants had actual or constructive knowledge that Avandia® posed a significant danger to anyone who used the drug, yet failed to take adequate or timely actions to prevent the injuries and deaths of users of Avandia® or to warn the public of these dangers.

70. GSK failed to adequately or appropriately disclose material information relating to the dangers associated with Avandia®. As a result, users of Avandia®, including Plaintiff, were unaware of these dangers, did not have adequate information to know the

[10] http://www.gsk.com/investors/reps06/annual_review_2006/key_products.htm

warnings signs of being exposed to rosiglitazone and were therefore unable to avoid injury caused by using this defective drug product.

71. Plaintiff has also incurred significant medical, hospital, rehabilitative and/or pharmaceutical expenses and/or other economic loss, loss of potential future earnings and/or net accumulations, loss of consortium and support, and will continue to incur such expenses, damages, and losses in the future.

CAUSES OF ACTION

AS AND FOR A FIRST CAUSE OF ACTION AGAINST DEFENDANTS FOR STRICT LIABILITY

72. Plaintiff repeats and realleges each and every allegation set forth above, as if fully set forth herein.

73. Defendants were, at all relevant times, engaged in the business of designing, creating, manufacturing, testing, labeling, packaging, supplying, marketing, selling, advertising, warning and otherwise distributing and placing in the stream of commerce Avandia®.

74. Plaintiff purchased and/or otherwise properly acquired Avandia®.

75. Avandia® reached Plaintiff, the ultimate user and consumer of this product, without any substantial change in its condition from the time it was manufactured and/or sold by Defendant.

76. Avandia®, when it reached Plaintiff, was in a defective condition and/or was in a condition that was unreasonably dangerous to the ultimate user or consumer. Said Avandia® was dangerous to an extent beyond that which would be contemplated by the ordinary user or consumer who purchased it with the ordinary knowledge common to the community as to the product's characteristics.

77. Plaintiff used Avandia®, as it was designed and intended to be used, and suffered a myocardial infarction as a result. Said injuries were the direct and proximate result of the product's defective and/or unreasonably dangerous condition.

78. As a direct and proximate result of Defendants' designing, creating, manufacturing, testing, labeling, packaging, supplying, marketing, selling, advertising, warning, and otherwise distributing and placing in the stream of commerce the Avandia® at issue in this lawsuit, Plaintiff suffered a heart attack.

79. The conduct of these Defendants, as set forth herein, was so outrageous and improper as to constitute willful, wanton, and reckless disregard for the safety of Plaintiff and the users and ultimate consumers of this product.

80. Defendants showed a reckless disregard for the public safety due to Defendants' acts and omissions as set forth in this Complaint. Defendants knew, or should have known, that there was a substantial and unnecessary risk of injury and death to those who used Defendants' product and Defendants failed to either determine the seriousness of the danger or reduce the risk to an acceptable minimal level.

81. There was a serious risk of harm to the public that resulted from the defect in Avandia®. Defendants were aware of the existence and seriousness of the defects prior to Plaintiff's heart attack. Defendants did not correct the defects, or take other steps to reduce the danger of injury. The amount it would have cost to correct the defect, or reduce the danger, was small compared to the risk the defect posed to consumers and users of Avandia®. The amount of revenue that Defendants received from sales of the defective drug was in the billion of dollars and profits in the hundreds of millions of dollars. Defendants attempted to conceal the defect or deceive the public about the safety of Avandia®; and, Defendants have very significant financial resources.

82. At all times relevant herein, Defendants manufactured, labeled, sold, distributed, supplied, dispensed, promoted and/or otherwise placing into the stream of commerce Avandia® which was defective, including one or more of the following particulars:

a. Avandia® contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks which exceeded the benefits of the drug;

b. When manufactured, packaged, assembled, labeled, distributed, supplied, and placed in the stream of commerce, the drug contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff risks which exceeded the benefits of the drug;

c. When manufactured, packaged, assembled, labeled, distributed, supplied, and placed in the stream of commerce, it was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with diabetes;

d. Avandia® was insufficiently tested;

e. Avandia® was marketed to be used in a combination which was known to Defendants to cause harmful side effects which outweighed any potential utility;

f. Avandia® is not safe for its intended use as an anti-diabetic agent;

g. GSK failed to provide adequate warning of the danger involved in the administration of rosiglitazone;

h. GSK failed to warn against the use of Avandia® without proper supervision and monitoring;

i. The defective Avandia® was defective in design and

formulation, making use of the product more dangerous than the ordinary consumer would expect and more dangerous than other risks associated with like products;

j. The defective Avandia® contained insufficient and/or incorrect warnings to alert consumers and users of the risks of adverse effects;

k. The defective medication was not safe for their intended use and were inadequately tested; and/or

l. The defective Avandia® was not accompanied by adequate instructions and/or warnings to fully apprise the prescribing physicians as well as the ultimate consumers, including Plaintiff, of the full nature or extent of the risks and side effects associated with its use.

83. Defendants knew and intended that the Avandia® would be used by such consumers without any inspection for defects, and would rely upon the representations made by Defendants on the product label and otherwise.

84. At the time of its manufacture and sale to Plaintiff, Avandia® was unsafe and defective to consumers using said product for its advertised purposes and in a reasonably foreseeable manner, in that it posed an unreasonably high risk of serious injury or death to consumers, which information was concealed by Defendants.

85. Prior to the manufacturing, sale and distribution of Avandia®, Defendants knew, or were reckless in not knowing, that Avandia® was in a defective condition.

86. Plaintiff used the product for its intended purpose and could not have discovered any defect therein through the exercise of due care.

87. Defendants, as manufacturers, marketers, distributors, and sellers of Avandia® are held to the level of knowledge of an expert in their field.

88. Plaintiff did not have substantially the same knowledge as an adequate warning from Defendants should have communicated to her.

89. But for the aforementioned defective and unreasonably dangerous conditions, the drug would not have been prescribed to Plaintiff, he would not have ingested the drug, and he would not have suffered a heart attack as alleged herein.

90. As a direct and legal result of the defective condition of the drug, Plaintiff suffered a heart attack.

91. By reason of the foregoing, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages in an amount to be determined by a jury, together with interest, costs of suit, and attorneys' fees.

AS AND FOR A SECOND CAUSE OF ACTION
AGAINST DEFENDANTS FOR FAILURE TO WARN

92. Plaintiff repeats and realleges each and every allegation set forth above, as if fully set forth herein.

93. Prior to Plaintiff's use of Avandia®, and during the period in which he used it, Defendants knew or had reason to know that Avandia® was dangerous and created an unreasonable risk of bodily harm to consumers.

94. GSK had a duty to exercise reasonable care to warn end users of the dangerous conditions or of the facts that made Avandia® likely to be dangerous.

95. Despite the fact that Defendants knew that the defective condition of Avandia® could cause serious and life threatening injuries to anyone who used it, Defendants took inadequate steps to ensure that said products were safe, to notify consumers of this danger, to prevent said products from being used by persons such as Plaintiff, and to exercise reasonable care in warning the medical community.

96. Plaintiff's injuries were a direct and proximate result of Defendants' failure to warn of the dangers of Avandia®.

97. Defendants' conduct, as set forth herein, was so outrageous and improper as to constitute willful, wanton, and reckless disregard for Plaintiff's safety. Defendants made conscious decisions not to redesign, revise the label, warn or inform the consuming public, in addition to suppressing this information from the general public. As such, Plaintiff is entitled to and hereby claims Punitive Damages in this action.

98. By reason of the foregoing, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages in an amount to be determined by a jury, together with interest, costs of suit, and attorneys' fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment as follows:

A. Awarding Plaintiff compensatory damages for physical injury, pain, suffering, and emotional distress;

B. Awarding Plaintiff treble damages so as to fairly and completely compensate Plaintiff for all damages, and to deter similar wrongful conduct in the future;

C. Awarding Plaintiff punitive damages in an amount sufficient to punish Defendants for their wrongful conduct and to deter similar wrongful conduct in the future;

D. Awarding Plaintiff costs and disbursements, costs of investigations, attorneys' fees and all such other relief available; and

E. Such further relief as this court deems necessary, just, and proper.

JURY DEMAND

Plaintiff hereby demands trial by jury on all issues raised in the Complaint which are triable by jury, pursuant to Tule 38 of the Federal Rules of Civil Procedure.

Dated: May 15, 2008
New York, NY

MURRAY, FRANK & SAILER LLP

By: _____
Marvin L. Frank (MF 1436)
275 Madison Avenue, 8th Floor
New York, N.Y. 10016
Tel: (212) 682-1818
Fax: (212) 682-1892

GLANCY BINKOW & GOLDBERG LLP
Marc L. Godino
Andrew Sohrn
1801 Avenue of the Stars, Suite 311
Los Angeles, CA 90067
Tel: (310) 201-9150
Fax: (310) 201-9160

GLASSMAN, EDWARDS, WADE AND WYATT, P.C.
B.J. Wade
26 N. Second Street
Memphis, TN 38103
Tel: (901) 527-4673
Fax: (901) 521-0940

Attorneys for Plaintiff